TEXAS Department of State Health Services

REGULATORY LICENSING UNIT
BLOODBORNE PATHOGEN CONTROL PROGRAM
Device Registration Application
(Health and Safety Code, Chapter 81, Subchapter H)
Return both the completed application, and non-refundable fee made payable to:
Texas Department of State Health Services, RLU, Food & Drug Licensing,-MC2003
P.O. Box 149347, Austin, Texas 78714-9347
For assistance in completing this application call (512) 834-6727

BBPATHOGEN
2511

BUDGET: **ZZ105**
FUND 107

LICENSE #

MANUFACTURER'S INFORMATION:

Manufacturer's Name: _____

Manufacturer's Mailing Address: _____

Manufacturer's Contact Person (Title): _____

Manufacturer's Phone #: _____

Manufacturer's Fax #: _____

Manufacturer's Email Address: _____

Manufacturer's Website (URL): _____

REGISTRATION FEES (Check one only): **(Non-refundable)**

☐ Initial Fee - $2,500.00 ☐ Renewal Fee - $2,000.00

PLEASE NOTE: Registration certificates are not transferable from one device to another or from one device name to another. Any request for transfer of registration due to a change in ownership shall be made in writing to the Texas Department of State Health Services.

PRODUCT IDENTIFICATION:

PRODUCT NAME: _____

MODEL NAME AND/OR NUMBER**:** _____

SYRINGE VOLUMES AVAILABLE (if applicable):

☐ 1 cc ☐ 3 cc ☐ 5 cc ☐ 10 cc ☐ 20 cc ☐ 30 cc ☐ 50 cc ☐ Insulin ☐ Tuberculin ☐ Other _____

NEEDLE GAUGES AVAILABLE (if applicable):

☐ 15g ☐ 16g ☐ 17g ☐ 18g ☐ 19g ☐ 20g ☐ 21g ☐ 22g ☐ 23g ☐ 25g ☐ Other _____

VERIFICATION: I SWEAR OR AFFIRM THAT ALL OF THE INFORMATION IN THIS APPLICATION IS TRUE AND CORRECT. I FURTHER CERTIFY BY SIGNATURE HEREON; THAT I AM AUTHORIZED TO EXECUTE THIS DOCUMENT ON BEHALF OF THE MANUFACTURER. I UNDERSTAND THAT REGISTRATION OF A NEEDLELESS SYSTEM DEVICE OR SHARPS DEVICE WITH ENGINEERED SHARPS INJURY PROTECTION WITH THE TEXAS DEPARTMENT OF STATE HEALTH SERVICES, DOES NOT CONSTITUTE AN ENDORSEMENT OR RECOMMENDATION OF THIS DEVICE.

_____ _____
Signature Date

_____
Printed Name & Title

PRODUCT INFORMATION: The following information needs to be provided only on initial application or if revisions have been made since the initial application was submitted.

COMMON NAME/TYPE (Please check only one category and one type of device):

☐ **Medication delivery devices:**

☐ Disposable syringe injection
☐ Needleless injection
☐ Prefilled medication syringe injection
☐ Other _____

☐ **Vascular access blood drawing devices:**

☐ Winged, steel-needle IV, butterfly
☐ Vacuum tube phlebotomy
☐ Arterial blood gas
☐ In-line blood collection
☐ Other_____

☐ **Surgical/ procedure needles:**

☐ Type:_____

☐ **Hemodialysis needle set:**

☐ Type:_____

☐ **IV Administration:**

☐ IV needleless administration
☐ IV protected needle administration
☐ IV catheter (stylet)
☐ Other _____

☐ **Puncture/incision administration devices:**

☐ Lancet
☐ Capillary blood access device
☐ Other _____

☐ **Safety dental syringe:**

☐ Type:_____

☐ **Other** _____

THE DEVICE IS A (check one only):

☐ **Needleless System** - A device that does not use a needle and that is used to withdraw body fluids after initial venous or arterial access is established, to administer medication or fluids, or for any other procedure involving the potential for an exposure incident.

☐ **Sharps Device with Engineered Sharps Injury Protection** - A sharps device containing a physical attribute that is built into a needle device used for withdrawing body fluids, accessing a vein or artery, or administering medications or other fluids and that effectively reduces the risk of an incident by a mechanism, such as barrier creation, blunting, encapsulation, withdrawal, retraction, destruction, or another effective mechanism, or is built into any other type of needle device, into a non-needle sharp, or into a non-needle infusion safety securement device that effectively reduces the risk of an exposure incident.

PHYSICAL ATTRIBUTES THAT EFFECTIVELY REDUCE THE RISK OF SHARP'S INJURY (check all that apply):

☐ barrier creation ☐ blunting ☐ encapsulation ☐ withdrawal/retraction ☐ other

DESCRIBE HOW THE SAFETY FEATURE IS ACTIVATED (if applicable - 300 characters or less):

_____

_____

_____

_____

_____

_____

PLEASE PROVIDE THE FOLLOWING INFORMATION WITH THE APPLICATION FORM (Check the box to indicate each is enclosed):

☐ Brief product description (400 characters or less)
☐ Photocopy of labeling submitted to FDA
☐ Product marketing or promotional literature
☐ Photocopy of original US FDA marketing clearance letter for 510(k) premarket notification or premarket approval (PMA) submission
☐ Photocopy of proof of exemption from 510(k) premarket notification (if applicable)
☐ If exempt, provide Code of Federal Regulation citation: _____